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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/611,658 | 06/30/2003 | Richard A. Thomas | P-RT 3600A | 1988 |
| 41552 | 7590 | 12/16/2005 | EXAMINER | |
| MCDERMOTT, WILL & EMERY | | | SKIBINSKY, ANNA | |
| 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 | | | ART UNIT | |
| SAN DIEGO, CA 92122 | | | PAPER NUMBER | |

1631

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/611,658 | | THOMAS, RICHARD A. | |
| | Examiner | | Art Unit | |
| | Anna Skibinsky | | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, 35, 36 and 66 drawn to a method and device for determining the nuclear packing efficiency (NPE) of a cell, classified in class 702, subclass 19.

If this Group is chosen, one specie from the below listed species A-E must be elected.

II. Claims 31-34 and 37-65, drawn to a method for determining an NPE for a population of cells, classified in class 702, subclass 19.

If this Group is chosen, one specie from the below listed species F-J must be elected.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I and II contain divergent method steps wherein Group I requires determining nuclear packing efficiency (NPE) by correlating the values of the biochemical component (BC) and the special displacement of the nucleus (SDN) while Group II requires identifying at least one cluster of the data points in addition to measuring a BC and SDN. Furthermore, Group II requires the manipulation of a cluster of data points while Group I does not. Thus, the subject matter of Group I and II are directed to different inventions and a search for both Groups entails an undue search burden.

Specie Election Regarding Group I

An election from each of the below species A through E, in Group I is required.

Specie (A)

Wherein the BC includes

Specie A1: nuclear envelope liquid (e.g. claim 10)

Specie A2: nuclear protein (e.g. claim 11)

Specie A3: nuclear water (e.g. claim 16)

Specie (B)

Wherein step (c) is performed

Specie B1: according to the formula shown in claim 17 (e.g. claim 17).

Specie B2: by determining a data point for BC and SDN on separate axes and determining NPE as a slope (e.g. claim 30).

Specie (C)

Wherein k_1 is

Specie C1: positive (e.g. claim 18)

Specie C2: is one (e.g. claim 21)

Specie (D)

Specie D1: Wherein the amount of $k_5(BC_2)^e$ is added to the value of BC (e.g. claim 24)

Specie D2: Wherein $k_5(BC_2)^e$ is to the value of SDN (e.g. claim 26)

Specie (E)

Wherein BC₂ is

Specie E1: DNA (e.g. claim 25)

Specie E2: RNA (e.g. claim 27)

Specie E3: is nuclear protein (e.g. claim 29)

Specie Election Regarding Group II

An election from each of the below species F through J, in Group II is required.

Specie (F)

Wherein the phenotype is

Specie F1: being of a different sex (e.g. claim 39)

Specie F2: being of a different tissue (e.g. claim 40)

Specie F3: being of a different species (e.g. claim 41)

Specie F4: being of a different state of differentiation (e.g. claim 42)

Specie F5: being at a preselected cell division cycle stage (e.g. claim 44)

Specie F6: being in an apoptotic stat (e.g. claim 48)

Specie F7: being of a disease state (e.g. claim 49)

Specie F8: aneuploidy (e.g. claim 54)

Specie F9: being neoplastic (e.g. 55)

Claims 31-34, 37, 38 and 43 are generic to this specie.

Specie (G)

Wherein one stage cycle is

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Specie G1: S (e.g. 45)

Specie G2: selected from a group consisting of G₀, G₁, G₂ and M (e.g. claim 47)

Claim 31-34, 37-44, and 48-66 are generic to this specie

Specie (H)

Wherein the disease state is

Specie H1: a genetic disease (e.g. claim 50)

Specie H2: sickle cell anemia (e.g. claim 51)

Specie H3: Down's syndrome (e.g. claim 52)

Specie H4: an autoimmune disease (e.g. claim 53)

Specie H5: none of the above

Claims 31-34, 37-49 and 54-66 are generic to the above specie.

Specie (I)

Wherein the indication of a different cell type is indicative of a

Specie I1: malignant cell (e.g. claim 57)

Specie I2: metastasizing cell (e.g. claim 59)

Claims 31-34, 37-56 and 61-66 are generic to the above specie.

Specie (J)

Wherein the cell is from

Specie J1: breast tissue (e.g. claim 61)

Specie J2: cervical tissue (e.g. claim 62)

Specie J3: lung tissue (e.g. claim 63)

Specie J4: tissue selected from the group listed in claim 64 (e.g. claim 64)

Specie J5: tissue selected from the group listed in claim 65 (e.g. claim 65)

Claims 31-34, 37-60 and 66 are generic to the above specie.

The above species are clearly distinct and entail a search burden which is undue if searched together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MARY K. ZEMAN
PRIMARY EXAMINER
Ar 1631
12/12/05